



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. FDA-2012-N-0205]

Agreements and Memoranda of Understanding Between the Food and Drug Administration and Other Departments, Agencies, and Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: This direct final rule makes technical changes that will update a requirement that many of our written agreements and memoranda of understanding (MOUs) with other departments, Agencies, and organizations be published in the Federal Register. Because we already post and will continue to post our ongoing agreements and MOUs with other departments, Agencies, and organizations on our Web site upon their completion, this requirement is no longer necessary. This direct final rule, accordingly, eliminates it. We are making these technical changes to conserve Agency time and resources, reduce government paperwork, and eliminate unnecessary Federal Register printing costs while continuing to afford public access to these documents. We are proceeding in accordance with our direct final rule procedures.

We are publishing a companion proposed rule under our usual procedure for notice-and-comment rulemaking to provide a procedural framework to finalize the rule in the event we receive any significant adverse comments and withdraw this direct final rule. The companion proposed rule and this direct final rule are substantively identical.

DATES: This rule is effective [INSERT DATE 135 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments on or before [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. If we receive no significant adverse comments within the specified comment period, we will publish a document confirming the effective date of the final rule in the Federal Register within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the Agency will publish a document in the Federal Register withdrawing this direct final rule before its effective date.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0205, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-0205 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional

information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 3, 1974 (39 FR 35697), we announced that copies of all our MOUs transacted with government Agencies and nongovernment organizations were available for public review at our offices during working hours and would be published in the Federal Register. We subsequently codified this policy in the Federal Register of December 24, 1974 (39 FR 44602 at 44651) and recodified it where it currently appears at § 20.108 (21 CFR 20.108) in the Federal Register of March 22, 1977 (42 FR 15616 at 15625).

Consumers, industry, professional groups, associations, educators, and other government Agencies had manifested widespread interest in the texts of these MOUs. The intent of § 20.108 was to promote transparency by providing access to these stakeholders.

This direct final rule will eliminate the requirement in current § 20.108(c) that our agreements and MOUs with other departments, Agencies, and organizations be published in the Federal Register on an individual basis and instead will require that they be posted on our Web site as completed. We increasingly rely on Internet-based communications to ensure and promote transparency in our operations and activities. So it is with this direct final rule, which merely recognizes and codifies our already established practice of making our ongoing agreements and MOUs with other departments, Agencies, and organizations publicly available on our Web site. At the time of this writing, each such publicly disclosable agreement and MOU can be accessed at one of the following three Food and Drug Administration (FDA) Web site locations:

<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm>;

<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/AcademiaMOUs/default.htm>; or

<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/OtherMOUs/default.htm>.

Because all publicly disclosable agreements and MOUs are posted on our Web site, it is no longer necessary to require, as does current § 20.108(b), that a permanent file of them be available for public review during working hours in the Agency's Freedom of Information Public Room. Accordingly, this rule will revise current § 20.108(b).

The public's access to an FDA Web site that is regularly updated to include agreements and MOUs as they are completed has already greatly enhanced the speed, ease, and convenience with which stakeholders can obtain and review these documents.

The rule's technical changes will lessen demands on the time of our staff and reduce the government paperwork and printing costs associated with Federal Register publication of newly completed agreements and MOUs with other departments, Agencies, and organizations. At the same time, it will continue to ensure, consistent with the underlying intent of § 20.108, the accessibility of records of widespread interest to consumers, industry, professional groups, associations, educators, and other government Agencies.

Currently, § 20.108(c) treats our cooperative work-sharing agreements with State or local government Agencies differently from our agreements and MOUs with other Agencies and organizations. Because these cooperative work-sharing agreements rarely vary significantly from one another, we decided against publishing their full texts in the Federal Register (51 FR 19851, June 3, 1986). Instead, since 1993, we have merely required them to be listed at least once every 2 years in the Federal Register (58 FR 48793, September 20, 1993). This direct final rule will end such disparate treatment. Revised § 20.108(b) will apply to all of our written agreements and MOUs with other departments, Agencies, and organizations, including cooperative work-sharing agreements with State or local government Agencies, except for signed agreements and MOUs relating to activities of our Office of Criminal Investigations, which are addressed in § 20.108(d), which will be revised and redesignated as § 20.108(c).

This direct rule does not amend § 20.108(a) (stating that our written agreements and MOUs are available for public disclosure).

## II. Direct Final Rulemaking

We have determined that the subject of this rulemaking is suitable and appropriate for a direct final rule because it is intended to make noncontroversial changes to existing regulations, and we do not anticipate receiving any significant adverse comments. In the Federal Register of November 21, 1997 (62 FR 62466), we announced the availability of the guidance document entitled "Guidance for FDA and Industry: Direct Final Rule Procedures." This guidance document may be accessed at

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm>.

Consistent with our procedures on direct final rulemaking, we are publishing elsewhere in this issue of the Federal Register a companion proposed rule. The companion proposed rule provides the procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as comments regarding this direct final rule.

We are providing a comment period on the direct final rule of 75 days after the date of publication in the Federal Register. If we receive any significant adverse comment, we intend to withdraw this direct final rule before its effective date by publication of a notice in the Federal Register within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether an adverse comment is significant and warrants withdrawing a

direct final rule, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending an additional change to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If any significant adverse comments are received during the comment period, we will publish, before the effective date of the direct final rule, a document withdrawing the direct final rule. If we withdraw the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule using the usual notice-and-comment procedures under the APA (5 U.S.C. 552 et seq.). If we receive no significant adverse comment during the specified comment period, we intend to publish a document in the Federal Register confirming the effective date within 30 days after the comment period ends.

### III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts;

and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule does not impose any significant costs, we certify that it will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. We do not expect this rule to result in any 1-year expenditure that would meet or exceed this amount.

#### IV. Paperwork Reduction Act of 1995

We have concluded that this direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) is not required.

#### V. Environmental Impact

We have determined under 21 CFR 25.33 that this direct final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.



## VI. Federalism

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this direct final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded this direct final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## VII. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document, and they may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 20 is amended as follows:

### PART 20--PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531-2582; 21 U.S.C. 321-393, 1401-1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b-263n, 264, 265, 300u-300u-5, 300aa-

1.

2. Amend § 20.108 as follows:

- a. Revise paragraph (b);
- b. Remove paragraph (c);
- c. Redesignate paragraph (d) as paragraph (c);
- d. Revise newly redesignated paragraph (c).

The revisions and redesignations read as follows:

§ 20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.

\* \* \* \* \*

(b) All written agreements and memoranda of understanding between FDA and any entity, including, but not limited to other departments, Agencies, and organizations will be made available through the Food and Drug Administration Web site at <http://www.fda.gov> once finalized.

(c) Agreements and understandings signed by officials of FDA with respect to activities of the Office of Criminal Investigations are exempt from the requirements set forth in paragraph (b) of this section. Although such agreements and understandings will not be made available through the FDA Web site, these agreements will be available for disclosure in response to a request from the public after deletion of information that would disclose confidential investigative techniques or procedures, or information that would disclose guidelines for law

enforcement investigations if such disclosure could reasonably be expected to risk circumvention of the law.

Dated: March 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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